

TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES	ii
I. Introduction.....	1
II. Nature of the Motion and Relief Sought.....	4
III. Facts	4
IV. Dr. Pieczenik Does Not State Any Claim for Relief	6
A. Legal Standard for a Motion to Dismiss for Failure to State a Claim	6
B. Patent Infringement.....	9
1. Dr. Pieczenik Does Not State a Claim for Direct Infringement.....	11
2. Dr. Pieczenik Does Not State a Claim for Indirect Patent Infringement.....	13
C. Dr. Pieczenik Does Not State a RICO Claim	14
D. Dr. Pieczenik Does Not State a Claim for Patent Invalidity	17
V. Dr. Pieczenik Lacks Standing to Seek Declarations of Patent Invalidity	17
VI. Conclusion	21

TABLE OF AUTHORITIES

	<u>Page</u>
<u>Cases</u>	
<i>Annulli v. Panikkar</i> , 200 F.3d 189 (3d Cir. 1999).....	16
<i>Armstrong v. Mukasey</i> , No. 08-6131, 2008 U.S. Dist. LEXIS 105189 (D.N.J. Dec. 22, 2008).....	8
<i>Aro Mfg. Co. v. Convertible Top Replacement Co.</i> , 377 U.S. 476 (1964).....	13
<i>Ashcroft v. Iqbal</i> , 129 S. Ct. 1937 (2009).....	<i>passim</i>
<i>Banks v. Commonwealth</i> , No. 09-1437, 2010 U.S. Dist. LEXIS 11975 (M.D. Pa. Jan. 4, 2010).....	8
<i>Bell Atlantic Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	<i>passim</i>
<i>Bender v. Motorola, Inc.</i> , No. 09-1245, 2010 U.S. Dist. LEXIS 26076 (N.D. Cal. Feb. 26, 2010).....	12
<i>Benitec Austl., Ltd. v. Nucleonics, Inc.</i> , 495 F.3d 1340 (Fed. Cir. 2007).....	18
<i>Broadcom Corp. v. Qualcomm Inc.</i> , No. 08-1829 WQH (LSP), 2009 U.S. Dist. LEXIS 21023 (S.D. Cal. March 12, 2009).....	17, 21
<i>Corebrace LLC v. Star Seismic LLC</i> , 566 F.3d 1069 (Fed. Cir. 2009).....	7
<i>Elan Microelectronics Corp. v. Apple, Inc.</i> , No. 09-01531, 2009 U.S. Dist. LEXIS 83715 (N.D. Cal. Sept. 14, 2009).....	13, 14
<i>Fowler v. UPMC Shadyside</i> , 578 F.3d 203 (3d Cir. 2009).....	7, 11
<i>Giles v. Medical Contractors CMS</i> , 680 F. Supp. 2d 633 (D. Del. 2010).....	8
<i>Gold v. Metz Lewis Law Firm, LLC</i> , No. 08-207, 2010 U.S. Dist. LEXIS 13566 (W.D. Pa. Feb. 17, 2010).....	15, 16

<i>H.J. Inc. v. Northwestern Bell Tel. Co.</i> , 492 U.S. 229 (1989).....	15
<i>Lum v. Bank of Am.</i> , 361 F.3d 217 (3d Cir. 2004).....	14
<i>Marshall-Silver Constr. Co. v. Mendel</i> , 894 F.2d 593 (3d Cir. 1990).....	15
<i>Marangos v. Swett</i> , 341 Fed. Appx. 752 (3d Cir. 2009).....	16
<i>McZeal v. Sprint Nextel Corp.</i> , 501 F.3d 1354 (Fed. Cir. 2007).....	10
<i>MedImmune, Inc. v. Genentech, Inc.</i> , 549 U.S. 118 (2007).....	19
<i>Michod v. Walker Magnetics Group, Inc.</i> , 115 F.R.D. 345 (N.D. Ill. 1987).....	14
<i>Munsif v. Cassel</i> , 331 Fed. Appx. 954 (3d Cir. 2009).....	15
<i>Oil, Chem. & Atomic Workers Int'l Union v. Missouri</i> , 361 U.S. 363 (1960).....	18
<i>Ondeo Nalco Co. v. Eka Chems., Inc.</i> , No. 01-537, 2002 U.S. Dist. LEXIS 26195 (D. Del. Aug. 10, 2002).....	12
<i>Pieczenik v. Dyax Corp.</i> , 76 Fed. Appx. 293 (Fed. Cir. 2003).....	1
<i>Pieczenik v. Dyax Corp.</i> , 226 F. Supp. 2d 314 (D. Mass. 2002).....	1
<i>Pieczenik v. Dyax Corp.</i> , No. 00-11370, 2003 U.S. Dist. LEXIS 18445 (D. Mass. Feb. 25, 2003)	1
<i>Prasco, LLC v. Medicis Pharm. Corp.</i> , 537 F.3d 1329 (Fed. Cir. 2008).....	15, 18, 19
<i>Rotella v. Wood</i> , 528 U.S. 549 (2000).....	16
<i>SanDisk Corp. v. STMicroelectronics, Inc.</i> , 480 F.3d 1372 (Fed. Cir. 2007).....	20

<i>Sedima, S.P.R.L. v. Imrex Co., Inc.</i> , 473 U.S. 479 (1985).....	14
<i>Shell Oil Co. v. Amoco Corp.</i> , 970 F.2d 885 (Fed. Cir. 1992).....	18
<i>Tabas v. Tabas</i> , 47 F.3d 1280 (3d Cir. 1993).....	15
<i>Taylor v. Books A Million, Inc.</i> , 296 F.3d 376 (5th Cir. 2002)	8
<i>Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.</i> , 482 F.3d 1330 (Fed. Cir. 2007).....	19
<i>View Eng'g, Inc. v. Robotic Vision Sys., Inc.</i> , 208 F.3d 981 (Fed. Cir. 2000).....	9

Statutes & Administrative Codes

U.S. CONST. ART. III, § 2.....	18
18 U.S.C. § 1961(1)	15, 16
18 U.S.C. § 1961(5)	15
28 U.S.C. § 2201(a)	18
35 U.S.C. § 271.....	13
35 U.S.C. § 271(a)	11
35 U.S.C. § 271(c)	13
35 U.S.C. § 271(e)(2).....	3
35 U.S.C. § 271(e)(4).....	3
35 U.S.C. § 281	15
35 U.S.C. § 302.....	21

Other Authorities

FED. R. CIV. P. 8	<i>passim</i>
FED. R. CIV. P. 12(b)(1).....	4, 17
FED. R. CIV. P. 12(b)(6).....	4, 6, 7, 10

FED. R. CIV. P. FORM 18.....	11
------------------------------	----

I. Introduction

Dr. George Pieczenik, appearing *pro se*, filed four suits in this district against 90 individually named defendants and either 61 or 244 “John Does” (depending on whether the complaints are read as separate or cumulative). Dr. Pieczenik does not allege that he is impecunious. He simply chooses to prosecute these litigations without retaining counsel.

The complaints allege that unspecified patents of the 90 plus defendants are invalid, that each of them has infringed his US Patent 5,866,363 (the “‘363 patent”) by doing unspecified “research, commercial and licensing activities,” and that they have “colluded and conspired” in unspecified ways that violate the Racketeering Institution and Corrupt Organization Act.

These complaints are not a new venture for Dr. Pieczenik. He is quite experienced as a *pro se* plaintiff.

In 2000, he sued Dyax Corporation, one of the defendants in his four new suits, on the same ‘363 patent pleaded in the complaints here. Initially, he had the assistance of counsel, but they parted ways after the claims were construed in a way that excluded the Dyax product. *See Pieczenik v. Dyax Corp.*, 226 F. Supp. 2d 314 (D. Mass. 2002); *Pieczenik v. Dyax Corp.*, No. 00-11370, 2003 U.S. Dist. LEXIS 18445 (D. Mass. Feb. 25, 2003) (granting summary judgment of noninfringement). He then pursued appeals through the Court of Appeals for the Federal Circuit on his own. *See Pieczenik v. Dyax Corp.*, 76 Fed. Appx. 293 (Fed. Cir. 2003).

Seven years ago he sued, again *pro se*, five individuals and six entities, in the Southern District of New York on a complaint that pleaded, in essentially identical language, the same generalized, unspecified claims of patent invalidity, patent

infringement and RICO violations that he now pleads here. *Pieczenik v. Bristol-Myers Squibb*, No. 03-CV-6336 (S.D.N.Y) (*See* Ex. 1¹ (docket sheet); Ex. 2 (original complaint); Ex. 3 (first amended complaint); Ex. 4 (second amended complaint)).

In January 2004, he sued, *pro se*, Merck & Co., Inc., in this district, alleging infringement of his '363 patent and RICO violations, in a case assigned to Judge Chesler. *Pieczenik v. Merck & Co., Inc.*, No. 04-CV-0182(SRC) (D.N.J. filed Jan. 15, 2004) (*See* Ex. 5 (complaint)).

Defendants Schering-Plough Products, Inc., Schering-Plough Corporation, Schering-Plough Biopharma Corporation, and Schering-Plough International are all direct or indirect subsidiaries of Merck & Co., Inc. - the same party involved in the prior New Jersey action. Defendants Schering-Plough Products, Inc. and Schering Corporation are direct subsidiaries of Merck & Co., Inc.; and Defendants Schering-Plough International and Schering-Plough Biopharma Corporation are subsidiaries of Schering Corporation. The Schering-Plough defendants are hereinafter referred to as "the Schering-Plough defendants".

Complaints must plead sufficient facts to make the asserted cause of action plausible. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007) ("*Twombly*"); *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) ("*Iqbal*"). Choosing to file these actions *pro se* does not give Dr. Pieczenik an exemption from the requirements for proper pleading nor does it give him a license to impose on defendants and the Court litigation that is based on unsupported speculation.

¹ "Ex __" refers to the exhibits attached to the Declaration of Dennis Gregory, Esq. filed together with this memorandum.

The complaint against the Schering-Plough defendants does not identify any activity that allegedly infringes the '363 patent. It does not identify a single patent owned by the Schering-Plough defendants that is allegedly invalid. It does not identify any act done by the Schering-Plough defendants that constitutes a RICO violation or any entity with whom it has purportedly “colluded and conspired.” Far from pleading a plausible cause of action, the complaint is self-evidently unsupported and incredible.

Moreover, even if the complaint had specified particular patents owned by the Schering-Plough defendants that Dr. Pieczenik contends are invalid, the Court would lack subject matter jurisdiction to adjudicate that claim. This Court is limited constitutionally to adjudicating actual “cases or controversies,” and precedent makes clear that standard is met for assertions of patent invalidity only when the challenger faces some prospective liability for infringement. The complaint does not plead any such risk, or any facts that support an inference that one exists. There is a mechanism by which parties who do not face an infringement risk can obtain a determination of the validity of a patent, but it is by reexamination proceedings in the USPTO, not in a District Court.

Finally, the complaint seeks an injunction under 35 USC § 271(e)(4). But that statutory provision applies only to defendants who do an act that constitutes infringement under 35 USC § 271(e)(2), which is filing an “abbreviated new drug” application seeking approval from the USFDA to market a generic copy of an approved drug covered by a patent owned by the plaintiff. The complaint does not allege that Dr. Pieczenik has an approved drug, or that the Schering-Plough defendants have filed an

application with the USFDA seeking to make a generic copy of it. There is no basis for the requested relief.

These are not minor technical defects remediable by providing a more detailed statement. They are substantive. A plaintiff, *pro se* or otherwise, must be in possession of a factual basis for its complaint and must plead those facts with sufficient precision to make the claim a plausible one. Dr. Pieczenik sued the Schering-Plough defendants as part of a grab bag of defendants, without factual justification for any of the claims he makes. The complaint against the Schering-Plough defendants should be dismissed for failure to state a claim on which relief can be granted, lack of subject matter jurisdiction, and failure of compliance with Rule 8 of the Federal Rules of Civil Procedure.

II. Nature of the Motion and Relief Sought

The Schering-Plough defendants move to dismiss each of the claims pursuant to Rule 8(a) and Rule 12(b)(6) of the Federal Rules of Civil Procedure for failure state a claim upon which relief can be granted. The Schering-Plough defendants also move to dismiss plaintiff's patent invalidity declaratory judgment claims for lack of subject matter jurisdiction, specifically standing, pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure.

III. Facts

On May 4 - 7, 2010, Dr. George Pieczenik, appearing *pro se*, filed four separate complaints in the district of New Jersey, assigned docket numbers 10-2230, 10-2253, 10-2296, and 10-2327. Each complaint purports to plead, in essentially identical language, claims of infringement of the '363 patent, invalidity of patents owned by the

defendants and RICO violations. Each was assigned to Judge Wolfson and Magistrate Judge Bongiovanni.

According to the complaint, the '363 patent "discloses and claims a method and means of identifying biological information." (Complaint ¶ 52). According to the face of patent, the '363 patent issued February 2, 1999 based on an application dated February 28, 1991. The February 28, 1991 application was a continuation-in-part of an application filed May 26, 1988, which in turn was a continuation of an application filed August 28, 1985.

In wholly conclusory terms, devoid of any allegations of fact, the complaint appears to assert four causes of action: (1) direct infringement of the '363 patent, (2) contributory infringement of the '363 patent, (3) a request for a declaratory judgment of invalidity of numerous unnamed patents assigned to the defendants, and (4) a civil RICO action founded on an alleged conspiracy to deny Dr. Pieczenik royalties.

Each of the causes of action is deficient – there is not a single fact that is alleged against the Schering-Plough defendants or any of the 90 other defendants to support any of the asserted claims. All that is in the complaint are boiler plate conclusory statements. There is no identification of which products or acts have allegedly infringed the '363 patent or which of any defendant's patents are allegedly invalid. The RICO claim is a naked assertion of conspiracy to harm him but alleges no predicate criminal acts. Finally, Dr. Pieczenik lacks standing to bring the invalidity declaratory judgment claims because he alleges no personal risk from any of the Schering-Plough defendants' patents.

IV. Dr. Pieczenik Does Not State Any Claim for Relief

A. Legal Standard for a Motion to Dismiss for Failure to State a Claim

In preparing a complaint, a plaintiff is obligated under FED. R. CIV. P. 8(a)(2) to include “a short and plain statement of the claim showing that the pleader is entitled to relief.” A complaint that fails to state a claim upon which relief can be granted must be dismissed pursuant to FED. R. CIV. P. 12(b)(6). *Twombly*, 550 U.S. at 570.

The Supreme Court in its *Twombly* and *Iqbal* opinions made clear that complaints must plead sufficient facts to make the asserted claims plausible. “While a complaint attacked by a Rule 12(6)(b) motion to dismiss does not need detailed factual allegations, a plaintiff’s obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555 (internal citations and quotations omitted); *Iqbal*, 129 S. Ct. at 1949 (“Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.”). Legal conclusions may provide the structure for the complaint, but the factual content must independently permit the court to infer more than the mere possibility of misconduct. *Id.* at 1950.

A complaint must contain sufficient factual matter “to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* at 1949 (*Twombly* citation and internal quotations omitted). The plausibility standard “asks for more than a sheer possibility that a defendant has acted unlawfully.” *Id.* The factual allegations made “must be enough to raise a right of relief above the speculative level.” *Twombly*, 550 U.S. at 555, *citing* 5 C. Wright & A. Miller, Federal Practice and Procedure § 1216 at 235-236 (3d ed. 2004).

Thus “[a]fter *Iqbal*, it is clear that conclusory or ‘bare-bones’ allegations will no longer survive a motion to dismiss.” *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). In *Fowler*, an employment discrimination case, the Third Circuit found that the plaintiff had adequately pleaded a claim for relief under the standards given in *Twombly* and *Iqbal*. However, unlike here, the complaint in *Fowler* “pleads how, when, and where UPMC allegedly discriminated against Fowler.” 578 F.3d at 205-06, 212. In the present case, the complaint provides no facts regarding how, when, or where the Schering-Plough defendants did any act that justifies any of the claims for relief.

Relying on *Twombly* and *Iqbal*, the Third Circuit² instructed district courts presented with a 12(b)(6) motion to dismiss to conduct a two-part analysis:

First, the factual and legal elements of a claim should be separated. The District Court must accept all of the complaint’s well-pleaded facts as true, but may disregard any legal conclusions. Second, a District Court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a plausible claim for relief. In other words, a complaint must do more than allege the plaintiff’s entitlement to relief. A complaint has to show such entitlement with its facts.

Fowler, 578 F.3d at 210-11. In deciding a motion to dismiss, a court takes all of the well-pleaded factual allegations as true, but “the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.” *Iqbal*, 129 S. Ct. at 1949. The Third Circuit’s instructions for deciding 12(b)(6) motions apply to all of the allegations made by Dr. Pieczenik, for the Supreme Court’s decision in *Twombly*

² Although patent cases are appealed to the Court of Appeals for the Federal Circuit, “[t]he question . . . whether a *Rule 12(b)(6)* motion was properly granted is a purely procedural question not pertaining to patent law, to which [the Federal Circuit] applies the rule of the regional . . . circuit.” *Corebrace LLC v. Star Seismic LLC*, 566 F.3d 1069, 1072 (Fed. Cir. 2009) (internal quotations omitted).

“expounded the pleading standard for all civil actions.” *Id.* at 1953 (“The decision [in *Twombly*] was based on our interpretation and application of Rule 8. That Rule in turn governs the pleading standard in all civil actions and proceedings in the United States district courts.”) (internal citations omitted).

Although Dr. Pieczenik is a *pro se* plaintiff, he is an experienced one,³ and as such should not be accorded any special deference or latitude. “While the general rule is that where a plaintiff is *pro se*, courts are to accord an even more liberal reading of the complaint . . . , in cases where there is an experienced *pro se* litigator, the Court need not accord such a liberal reading.” *Banks v. Commonwealth*, No. 09-1437, 2010 U.S. Dist. LEXIS 11975, at *7 (M.D. Pa. Jan. 4, 2010); *see also Armstrong v. Mukasey*, No. 08-6131, 2008 U.S. Dist. LEXIS 105189, at *4 (D.N.J. Dec. 22, 2008) (declining to construe *pro se* plaintiff’s request for injunctive relief as a writ for habeas corpus because plaintiff had represented himself in two related matters).

In any event, even if the court were inclined to make accommodations for Dr. Pieczenik as a *pro se* litigant, his complaint is not exempt from the requirements for proper pleading. “[R]egardless of whether the plaintiff is proceeding *pro se* or is represented by counsel, conclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss.” *Taylor v. Books A Million, Inc.*, 296 F.3d 376, 378 (5th Cir. 2002); *see also Giles v. Medical Contractors CMS*, 680 F. Supp. 2d 633, 637 (D. Del. 2010) (applying the *Iqbal* standard and dismissing *pro se* plaintiff’s complaint because “the complaint contains conclusory allegations without facts to support a claim”).

³ See Introduction, *supra*, at 1-2.

Litigation is not a license for a plaintiff to use the discovery process to find out if it has the necessary basis for a claim. A deficient claim, such as every one of Dr. Pieczenik's, should "be exposed at the point of minimum expenditure of time and money by the parties and the court." *Twombly*, 550 U.S. at 558, *citing* Wright & Miller § 1216 at 233-34. Rule 8 "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Iqbal*, 129 S. Ct. at 1950. Discovery is inevitably costly and protracted, thus "it is one thing to be cautious before dismissing a [] complaint in advance of discovery, but quite another to forget that proceeding to [] discovery can be expensive." *Twombly*, 550 U.S. at 558 (internal citation omitted); *see also View Eng'g, Inc. v. Robotic Vision Sys., Inc.*, 208 F.3d 981, 986 (Fed. Cir. 2000) ("A patent suit can be an expensive proposition. Defending against baseless claims of infringement subjects the alleged infringer to undue costs . . ."). Even minimal discovery in the action could be burdensome based on the lack of notice provided by Dr. Pieczenik's complaint.

Applying the above pleadings standards, the patent infringement allegations, conspiracy allegations, and patent invalidity allegations asserted against the Schering-Plough defendants are addressed separately below. All are pleaded as "naked assertions." Thus, the complaint fails *in toto* to render plaintiff's entitlement to relief plausible and should be dismissed. Dr. Pieczenik should not be permitted to subject the Schering-Plough defendants (or any of the 90 plus defendants) to what could be burdensome discovery, magnified by his failure to conduct an adequate pre-suit investigation and to provide the Schering-Plough defendants with sufficient notice.

B. Patent Infringement

While a plaintiff in a patent infringement suit "is not required to specifically include each element of the claims of the asserted patent" in the complaint,

the patentee must nonetheless “plead facts sufficient to place the alleged infringer on notice as to what he must defend.” *McZeal v. Sprint Nextel Corp.*, 501 F.3d 1354, 1357 (Fed. Cir. 2007).⁴ The factual detail in the complaint regarding any alleged infringement by the Schering-Plough defendants is not just insufficient, it is nonexistent. With respect to the alleged infringement of his patent, Dr. Pieczenik’s complaint states only,

By virtue of defendant’s research, commercial and licensing activities, defendants have infringed upon plaintiff’s patent and have contributed to others infringing on plaintiff’s patent.

This action involves a nexus of infringement in New Jersey. Defendants . . . as corporations and individuals allow for a situation where their management, scientists and sales personnel 1) infringe on the ‘363 patent, 2) create companies which infringe the ‘363 patent and 3) collaborate with companies which infringe on the ‘363 patent.

(Complaint ¶¶ 55, 57). Dr. Pieczenik’s bare allegation of infringement does not specify the objects or acts of that infringement, and as such, does not provide the Schering-Plough defendants with the type of notice of claim contemplated by Rule 8. His complaint, even if read in the most charitable manner, alleges nothing more than an allegation that because the Schering-Plough defendants are pharmaceutical companies, their general activities as pharmaceutical companies infringes his patent. The pleading

⁴ Although the Federal Circuit in *McZeal* found that the plaintiff there met the low bar for *pro se* litigants to avoid a 12(b)(6) dismissal of his complaint, the allegations of infringement there were considerably more detailed than what is found in Dr. Pieczenik’s present complaint against Schering. *McZeal*, 501 F.3d at 1358. The complaint in *McZeal* described the means by which the defendants allegedly infringed, referring to specific products. *Id.* at 1357. In the present case, however, the complaint lacks any facts regarding how or with what products or activities Schering allegedly infringes the asserted patent.

standard under Rule 8 “demands more than an unadorned, the defendant-unlawfully-harmed-me accusation,” which is what Dr. Pieczenik’s two statements regarding infringement amount to. *Iqbal*, 129 S. Ct. at 1949.

Following the instruction of the Third Circuit in *Fowler*, if the present complaint contained well-pleaded factual allegations of infringement, this Court would assume their veracity and determine if they plausibly suggest an entitlement to relief. *See also Iqbal*, 129 S. Ct. at 1951. In this case, however, that cannot be done. Dr. Pieczenik’s assertion of infringement is a legal conclusion, and as such is not entitled to the assumption of truth. Moreover, as Dr. Pieczenik’s complaint does not actually contain any factual allegations regarding infringement, there is nothing with which the court can determine the plausibility of relief.

1. Dr. Pieczenik Does Not State a Claim for Direct Infringement

A patent is directly infringed when “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore.” 35 U.S.C. § 271(a). Even the barest sample complaint for patent infringement, as set forth in FED. R. CIV. P. Form 18, requires, *inter alia*, a statement that the defendant has been infringing the asserted patent by “making, selling, and using [identified products] that embody the patented invention.”

In contrast, Dr. Pieczenik’s complaint does not identify anything that is or has been made, used or sold by the Schering-Plough defendants in their “research or commercial” activities that purportedly infringes his patent, and “licensing” (apart from the fact that the complaint does not say what it is that is licensed) is not an act of infringement under the statute. Dr. Pieczenik alleges direct infringement of the ‘363

patent without specifying what it is that allegedly directly infringes. The less than bare bones complaint nowhere identifies anything that the Schering-Plough defendants make, sells, or use that embodies the allegedly infringed invention of the '363 patent. Without these facts, the complaint cannot survive the first step of the Third Circuit's two part analysis – the complaint is merely a series of legal conclusions, and there are no facts to accept as true. And as there are no facts with which to work, it is impossible to conduct the second step of the analysis, which calls for the court to determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a plausible claim for relief.

As courts have explained, the touchstone for the Rule 8 analysis is whether the complaint gives fair notice. In *Bender v. Motorola, Inc.*, a district court dismissed a complaint that “fails to specify any particular accused devices and instead, simply alleges that broad categories of Defendant’s products are infringing.” No. 09-1245, 2010 U.S. Dist. LEXIS 26076, at *1 (N.D. Cal., Feb. 26, 2010). The court found the complaint “too conclusory to provide ‘fair notice’ of the basis of Plaintiff’s claim that Defendant infringed the [patent-in-suit].” *Id.* at *3; *see also Onda Nalco Co. v. Eka Chems., Inc.*, No. 01-537, 2002 U.S. Dist. LEXIS 26195, at **4-5 (D. Del., Aug. 10, 2002) (dismissing counterclaims where, except for providing a product number, “the pleadings are too vague to provide plaintiff with fair notice of which products are accused of infringing defendant’s patents.”). Similarly, the Schering-Plough defendants are in no way given fair notice of the claims against them that allegedly constitute direct infringement of the '363 patent.

2. Dr. Pieczenik Does Not State a Claim for Indirect Patent Infringement

The complaint also includes conclusory allegations of contributory infringement, stating only that the unspecified “research, commercial and licensing activities, . . . have contributed to others infringing on plaintiff’s patent.” (Complaint ¶ 55).

Liability for contributory infringement requires “a showing that the alleged contributory infringer knew that the combination for which his component was especially designed was both patented and infringing.” *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488 (1964). There are four elements: (1) direct infringement by another, (2) knowledge that the component was designed for an infringing use, (3) that the component is a material part of the patented product, and (4) the component is not a staple product of commerce. 35 U.S.C. § 271(c).

The complaint nowhere identifies who the “others” are or what acts those “others” did that infringe the ‘363 patent. Beyond that, it does not include any allegation regarding the remaining three elements. It does not inform of any infringing products, does not identify what are the material components of those infringing products, and does not even aver that they were knowingly designed for infringing use, or are not staple products of commerce.

A district court recently dismissed contributory infringement claims on similar facts in *Elan Microelectronics Corp. v. Apple, Inc.*, No. 09-01531, 2009 U.S. Dist. LEXIS 83715 (N.D. Cal. Sept. 14, 2009). In *Elan*, Apple pleaded “‘on information and belief’ that Elan ‘has been and is currently, directly and/or indirectly infringing, in violation of 35 U.S.C. § 271’ the specified patents ‘through its design, marketing,

manufacture and/or sale of touch sensitive input devices or touchpads, including but not limited to the Smart-Pad.” *Id.* at **4-5 (quoting Apple’s Answer). The Court dismissed those claims because “this pleading plainly falls within the prohibition against “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements.”” *Id.* at *5 (quoting *Iqbal*, 129 S. Ct. at 1949). Indeed, the contributory infringement claim here is even less substantial than the claim in *Elan – Apple* at least alleged a directly infringing product.

The contributory infringement claims should be dismissed for inadequate pleading and failure to state a claim.

C. Dr. Pieczenik Does Not State a RICO Claim

Dr. Pieczenik’s Racketeer Influenced and Corrupt Organization (“RICO”) claim is entirely conclusory. To the extent any meaning can be gleaned from the language, it appears that he alleges that the Schering-Plough defendants and other defendants have conspired and colluded together to infringe the ‘363 patent and to deny him royalties. At minimum, and accepting that at face value, it fails to allege any predicate acts of racketeering. Claims of patent infringement – a *civil* tort – cannot be recast as the predicate *criminal* acts of racketeering. *Michod v. Walker Magnetics Group, Inc.*, 115 F.R.D. 345, 347 (N.D. Ill. 1987) (“Congress defined ‘racketeering activity’ with considerable specificity, and patent infringement is not within the definition.”).

“In order to plead a violation of RICO, plaintiffs must allege (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity.” *Lum v. Bank of Am.*, 361 F.3d 217, 223 (3d Cir. 2004) (*citing Sedima, S.P.R.L. v. Imrex Co., Inc.*, 473 U.S. 479, 496 (1985)). A pattern of racketeering activity is defined as at least two

specific acts of “racketeering activity”, commonly known as predicate acts. 18 U.S.C. § 1961(5).

Racketeering activity is defined in 18 U.S.C. § 1961(1). Generally, racketeering activity includes serious federal or state criminal offenses, such as murder, kidnapping, money laundering, etc. A predicate act must “amount to or pose a threat of continued criminal activity.” *H.J. Inc. v. Northwestern Bell Tel. Co.*, 492 U.S. 229, 239 (1989); *see also Munsif v. Cassel*, 331 Fed. Appx. 954 (3d Cir. 2009) (non-precedential) (finding that *pro se* plaintiff’s allegations of examination board’s interference with his certification testing did not constitute predicate acts under the RICO statute); *Marshall-Silver Constr. Co. v. Mendel*, 894 F.2d 593, 598 (3d Cir. 1990) (*overruled in-part on other grounds by Tabas v. Tabas*, 47 F.3d 1280 (3d Cir. 1993)) (when the allegations of the complaint, taken as true, do not support the existence of either long-term criminal conduct or the threat thereof, dismissal is appropriate).

The complaint alleges no acts that could constitute “racketeering activity” under 18 U.S.C. § 1961(1) or a “pattern of racketeering activity.” Patent infringement is not and cannot be “racketeering activity.” Patent infringement is not a crime – it is a federal civil tort. *See* 35 U.S.C. § 281. Indeed “absent action by the patentee, a potential competitor . . . is legally free to market its product in the face of an adversely-held patent.” *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008) (internal citation omitted). Faced with a similar situation, a district court in the Third Circuit recently held that a *pro se* plaintiff allegedly injured by, *inter alia*, “loss of patent royalties due him and future royalty earnings” failed to state a RICO claim. *Gold v. Metz Lewis Law Firm, LLC*, No. 08-207, 2010 U.S. Dist. LEXIS 13566, at **14-15 (W.D. Pa.

Feb. 17, 2010). The court held that alleged predicate acts arising from patent law do not constitute racketeering activity under Section 1961(1). *Id.* The court reasoned that “[f]undamentally, Plaintiff is complaining about conduct which may be unlawful under civil tort law principles and/or federal patent law, but which is not indictable under the federal criminal laws in question.” *Id.* at *14; *see also Annulli v. Panikkar*, 200 F.3d 189, 200 (3d Cir. 1999) (*overruled on other grounds by Rotella v. Wood*, 528 U.S. 549 (2000)) (mere torts are not racketeering).

Finally, even if the underlying theory were legally viable, this Court should reject the RICO claim under *Iqbal* and *Twombly*. The allegations are nothing more than legal conclusions devoid of any supportive facts and are therefore not entitled to any presumption of correctness. As the Supreme Court stated in *Iqbal*, courts “are not bound to accept as true a legal conclusion couched as a factual allegation” in deciding a motion to dismiss. *Iqbal*, 129 S. Ct. 1937, 1950 (citing *Twombly* at 555); *see also Marangos v. Swett*, 341 Fed. Appx. 752, 757 (3d Cir. 2009) (non-precedential) (conclusory predicate acts allegations not presumed true; insufficient to say “Defendants...are involved in a cover-up and criminal and civil conspiracy to violate Plaintiff’s...fundamentally secured Property Rights”).

Ultimately, even were the final step of the Third Circuit’s two-part analysis reached, the allegations are not plausible; they are incredible in every sense of the word. The complaint offers no plausible reason as to why essentially the entire biopharmaceutical industry would conspire against the plaintiff.

The RICO claims should be dismissed.

D. Dr. Pieczenik Does Not State a Claim for Patent Invalidity

Dr. Pieczenik has requested that this court declare invalid “claims in defendant’s patents [that] relate to the combinatorial libraries and biologics, therein derived; they are substantially similar to claims in plaintiff’s patent” (Complaint ¶ 56).

To the extent Dr. Pieczenik seeks an adjudication of the validity of any patent, Dr. Pieczenik has failed to state a claim. First, the complaint does not explicitly request declaratory relief. Second, and more importantly, the complaint does not name any patents of the Schering-Plough defendants (or any other defendant) that are alleged to be invalid. At a minimum, the complaint must identify the specific patents that are alleged to be invalid. *Broadcom Corp. v. Qualcomm Inc.*, No. 08-1829 WQH (LSP), 2009 U.S. Dist. LEXIS 21023, at *17-18 (S.D. Cal. March 12, 2009).

The declaratory judgment claims should be dismissed.

V. Dr. Pieczenik Lacks Standing to Seek Declarations of Patent Invalidity

Dr. Pieczenik asserts in his complaint that unnamed patents owned by the Schering-Plough defendants (and by the other 90 named defendants) are invalid. To the extent the complaint is construed as seeking an adjudication of the validity of any patent (which is not specifically requested in the Prayer For Relief), it asks for an advisory opinion about patents that pose no risk to Dr. Pieczenik, and should be dismissed for lack of subject matter jurisdiction. FED. R. CIV. P. 12(b)(1).

The complaint alleges that the Schering-Plough defendants and other defendants “own, use and have filed patents claiming methods, products and biological intermediates used in creating and/or using peptide and antibody combinatorial libraries,” and that “[t]o the extent that the claims in defendant’s patents relate to the combinatorial

libraries and biologics, therein derived; they are substantially similar to claims in plaintiff's patent, defendant's patents are invalid." (Complaint ¶¶ 53, 56).

Critically, Dr. Pieczenik does not allege (1) any act of his own that put him at present or future risk of patent infringement liability; or (2) any affirmative action taken by the Schering-Plough defendants (or any other named defendant) against him. The absence of either is fatal to subject matter jurisdiction.

The Declaratory Judgment Act permits the federal courts to "declare the rights and other legal relations of parties" only if there is an "actual controversy" between the parties. 28 U.S.C. § 2201(a). *See also Prasco*, 537 F.3d at 1335. The "actual controversy" requirement is a Constitutional limitation on federal courts' power. *See id.*; U.S. Const. art. III, § 2. Federal courts are to decide only "actual controversies by a judgment which can be carried into effect, and not to give opinions upon moot questions or abstract propositions, or to declare principles or rules of law which cannot affect the matter in the issue in the case before it." *Oil, Chem. & Atomic Workers Int'l Union v. Missouri*, 361 U.S. 363, 367 (1960).

A plaintiff must prove declaratory judgment jurisdiction by a preponderance of the evidence. *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 887 (Fed. Cir. 1992); *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007). Whether an actual case or controversy exists for a declaratory judgment of invalidity is governed by Federal Circuit law. *See Shell Oil*, 970 F.2d at 888, n.4.

Declaratory judgment jurisdiction lies if "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a

declaratory judgment.” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (holding that a real controversy existed because the declaratory plaintiff was selling a product and faced infringement damages if it ceased paying royalties). “[T]he dispute [must] be definite and concrete, touching the legal relations of parties having adverse legal interests; and . . . it [must] be real and substantial and admit of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.” *Id.* (internal quotations omitted); *see also Prasco*, 537 F.3d at 1336.

Thus, to meet the “immediacy and reality” requirement, “the plaintiff must allege (1) an injury-in-fact, *i.e.*, a harm that is concrete and actual or imminent, not conjectural or hypothetical, (2) that is fairly traceable to the defendant’s conduct, and (3) redressable by a favorable decision.” *Prasco*, 537 F.3d at 1338 (internal quotations omitted); *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1337 (Fed. Cir. 2007) (“An injury-in-fact must be ‘personal,’ ‘concrete and particularized,’ and ‘actual or imminent.’”). “Absent an injury-in-fact fairly traceable to the patentee, there can be no immediate and real controversy.” *Prasco*, 537 F.3d at 1338. “This justiciability problem can also be viewed through one of the prongs of the ripeness doctrine, whether the complained-of-conduct has an ‘immediate and substantial impact’ on the plaintiff such that withholding court consideration would cause hardship to the plaintiff.” *Id.* at 1338, n.6.

In a patent context, jurisdiction will not “arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee.” *SanDisk*

Corp. v. STMicroelectronics, Inc., 480 F.3d 1372, 1381 (Fed. Cir. 2007); *see also Prasco*, 537 F.3d at 1338 (“*MedImmune* does not change our long-standing rule that the existence of a patent is not sufficient to establish declaratory judgment jurisdiction.”). “The mere existence of a potentially adverse patent does not cause an injury nor create an imminent risk of an injury; absent action by the patentee, a potential competitor is legally free to market its product in the face of an adversely-held patent.” *Prasco*, 537 F.3d at 1338 (internal quotations omitted).

An actual “controversy must be based on a *real* and *immediate* injury or threat of future injury that is *caused by the defendants*.” *Id.* at 1339. “[T]he Supreme Court has emphasized that a fear of future harm that is only subjective is not an injury or threat of injury caused by the defendant that can be the basis of an Article III case or controversy.” *Id.* at 1338. In addition, a court should consider “whether there has been potentially infringing activity or meaningful preparation to conduct potentially infringing activity.” *Id.* at 1336 n.4.

Here, there is no injury-in-fact to Dr. Pieczenik fairly traceable to the Schering-Plough defendants or any other defendant patentee. The mere fact that the parties have patents in a similar field (if, indeed, that is factually correct) does not create a justiciable controversy between them. In addition to not identifying a single patent that is allegedly invalid, Dr. Pieczenik does not allege that he has engaged in any potentially infringing activity or meaningful preparation for potentially infringing activity. The mere fact that the plaintiff owns a patent in the same technology area does not give him standing to challenge other patents in that technology area.

In addition, Dr. Pieczenik alleges no affirmative act by Defendants that would place him at risk of infringement liability. He does not allege that the Schering-Plough defendants (or any other defendant) have so much as implied that any of plaintiff's present or past activities would infringe any patents.

The facts here are similar to *Broadcom Corp.*, 2009 U.S. Dist. LEXIS 21023. In that case, Broadcom requested a declaration of patent misuse, patent exhaustion, and that Qualcomm's patents and licenses were unenforceable. *Id.* at **5-6. Yet, out of thousands of patents owned by Qualcomm, Broadcom did not identify a single patent in its complaint. *Id.* at *16. The court found that Broadcom could not meet the requirements for declaratory judgment jurisdiction because it did not identify any patents in the suit and did not provide any affirmative acts by the defendants. *Id.* at **16-18. For similar reasons, Dr. Pieczenik's declaratory judgment of patent invalidity should be dismissed for lack of subject matter jurisdiction.

Finally, if, in fact, there are any patents owned by the Schering-Plough defendants whose validity Dr. Pieczenik has a basis to challenge, there is a forum in which he can do that, albeit not in this Court. He can pursue the remedy created precisely for that purpose - a request for reexamination of the subject patent in the USPTO in which he can cite his own '363 patent and any other prior art he deems relevant. 35 U.S.C. § 302.

VI. Conclusion

In sum, Dr. Pieczenik's complaint fails to satisfy the most basic pleading requirements. The complaint does not state a claim for patent infringement, patent invalidity, or a RICO claim. In addition Dr. Pieczenik lacks standing to seek a declaratory judgment for patent invalidity (if that is his intent). Although Dr. Pieczenik is

a *pro se* plaintiff, he is not new to patent litigation, and he is not exempt from providing sufficient factual allegations from which the Court can determine the plausibility of his claims. The requirements of proper pleading are necessary to give the Schering-Plough defendants fair notice of the claims against them, but Dr. Pieczenik's complaint is substantively deficient and falls far short of providing such notice. Because Dr. Pieczenik's complaint fails to state a claim upon which relief may be granted, and lacks subject matter jurisdiction, it should be dismissed.

Respectfully submitted,

Date: June 4, 2010

/s/ William J. Heller

William J. Heller
Jonathan M.H. Short
Cynthia S. Betz
Symone J. Redwine
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Telephone: (973) 622-4444
Facsimile: (973) 624-7070

Of Counsel

Robert L. Baechtold
FITZPATRICK CELLA HARPER &
SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Telephone: (212) 218-2100
Facsimile: (212) 218-2200

Attorneys for Defendants
Schering-Plough Products, Inc., Schering-
Plough Biopharma, Schering Corporation,
and Schering-Plough International, Inc.

FCHS_WS 5157892_1